

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
Issues needing discussion with EPA			
Calculation of additive risks to fish for dietary LOE	Non-directed comment: 23	The EPA problem formulation does not call for an analysis of chemical additivity other than for dioxin-like chemicals. In resolution of directed comments (uncertainties that underestimate risk), the LWG agreed to add a discussion of this uncertainty in the uncertainty analysis but not data analyses.	The LWG's general response is sufficient and appropriate to address this comment.
Assess risk at the individual sample scale vs. 95% UCL over larger spatial extent	Non-directed comments: 17, 37, 40, 43, 85, 107, 122, 131, 149, 151, 131, 135, 149	<p>A point-by-point assessment is not appropriate for the assessment endpoints identified by EPA for the BERA.</p> <p>Consistent with the resolution to directed comments on Eco HQs\geq1, the LWG agrees to present location-specific TRV exceedances for individual samples (as was done in the draft BERA) and identify HQs\geq1 as posing potentially unacceptable risks. Also consistent with the resolution to directed comments on Eco HQs\geq1, the spatial extent, magnitude, and ecological significance of these HQs will be evaluated. The LWG understands EPA's position to be that any HQ \geq 1 at any point in the Study Area is conclusive evidence of <i>potentially</i> unacceptable risk. The LWG wants to be clear that limited spatial extent and/ or low magnitude HQs \geq 1 are not necessarily ecologically significant and that in such cases unacceptable risk is implausible.</p> <p>Regarding risks to all fish receptors from water (comment 131), the LWG contends that UCLs calculated over the home ranges presented in the draft BERA for each fish receptor are the appropriate</p>	For all lines of evidence the exposure areas defined for dietary exposure to ecological receptors are appropriate for all lines of evidence (sediment, water, diet, and tissue). Potentially unacceptable risks will be defined as HQs \geq 1 calculated over the specified foraging area. Specifically the exposure point concentration (EPC) will be calculated as the 95% UCL of the exposure media (i.e., sediment, water, diet, tissue) calculated over the foraging area. The HQ will be calculated as the EPC divided by the appropriate TRV. If insufficient data are available within the foraging area to calculate a UCL, the data rules defined in the BERA will be used to determine the EPC (e.g., maximum concentration)

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
		final step in HQ analyses for identifying potentially unacceptable risks.	
Fish tissue TRVs Antimony, Cd, PCBs, DDX, Hg, Lindane,	Non-directed comments: 47, 110, 112, 119, 123, 124, 139, 147, 202, 203, 204, 205,	<p>Regarding comments 47, 110, 123, 139, and 202, 203, 204, TRV tables presented in draft BERA Attachment 9 include all of and only those studies with LOELs and NOELs agreed to between the LWG and EPA based on meetings and discussion to revise the EPA provided tissue TRVs. The TRVs presented in the draft BERA were derived using @Risk software and agreed species sensitivity distribution (SSD) methods. LWG will provide the output files.</p> <p>Comment 112 - It is reasonable to assume that adverse effects occurred at the highest tissue concentration observed during the time course of the study, especially since no adverse effects were observed at this concentration in related studies reported in the same paper.</p> <p>Comment 110 - the fish TRV reconciliation table that the LWG sent to EPA in Nov of 2008 had an EPA recommended TRV of 9 mg/kg for antimony. No changes are proposed by the LWG.</p> <p>Comments 110, 124 - As agreed to by EPA in the document entitled "EPAFishTissueTRVResponse122808" e-mailed from Eric Blischke to the LWG on 12/22/08, a literature-based LOAEL could not be derived. Therefore, BEHP concentrations were compared to the only literature-based NOAEL identified ($\geq 9.6 \mu\text{g/g ww}$). An exceedence to a NOAEL is not indicative of risk, and</p>	<p>EPA agreed that the appropriate fish tissue TRVs for the revised BERA are those derived using all of and only those papers agreed to between EPA and the LWG in the series of communications beginning with EPA's initial submittal of the tissue TRVs in August 2008 and ending with the EPA letter to the LWG on January 22, 2008.</p> <p>Specifically, the set of TRV tables delivered from the LWG to EPA on November 20, 2008 with the following changes are the basis of the TRVs. Changes to these tables include: addition of sac-fry studies as directed by EPA in a letter sent from EPA on December 22, 2008; addition of behavior studies determined by EPA to be ecologically significant as directed by EPA in a letter dated January 23, 2009; and addition of specific Great Lakes studies with elevated contaminant levels in control fish as directed by EPA a letter to LWG on January 23, 2009. As agreed by EPA, it is appropriate that the statistical distribution of the data be</p>

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November 18, 2010

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		<p>therefore this exceedance will not be included in Table 7-10.</p> <p>Comment 205 - As presented in draft BERA Attachment 9, the final TRV tables agreed to between the LWG and EPA, the Ramamoorthy 1985 behavioral LOAEL was rejected for inclusion in TRV derivation. The lowest LOAEL was 0.2 mg/kg ww as reported in Schimmel et al. 1977. Too few acceptable studies were available to derive a 5th or 10th percentile TRV following the EPA-LWG agreed TRV derivation methods.</p> <p>Comments 119, 147 - Several of the TRVs have significant uncertainties not specifically related to the SSD methodology. TRV uncertainties are discussed in Section 7.1.3 and summarized in Table 7-5 and 11-2. The uncertainties presented in Table 7-13 are consistent with the uncertainties raised in these earlier sections of the document.</p>	<p>determined using @RISK software. The @RISK output files will be included in the revised BERA.</p> <p>The above changes to the November 20, 2008 TRV tables resulted in the TRVs presented in attachment 9 of the revised BERA. Accordingly, the only fish tissue-residue TRVs that will change in the revised BERA are those discussed below.</p> <p>Specific changes that will be included in the revised BERA are: the antimony LOAEL TRV will be revised by applying an acute to chronic ratio.</p> <p>The mercury TRV will be revised to include the correct value for the Sandheinrich and Miller (2006) LOAEL which was erroneously reported in the published paper.</p> <p>The LOAEL from Allison will not be changed from that used in the DDx TRV derivation in the draft BERA, unless EPA specifically requires this change.</p>
Inclusion of carp data in fish tissue residue analysis	Non-directed comments: 106, 109, 120, 197	<p>The LWG agrees to discuss the carp data for chemicals evaluated using the tissue-residue approach in the uncertainty analysis for the omnivorous fish population assessment endpoint.</p> <p>Whole-body fish tissue for carp was analyzed for</p>	EPA agreed that consistent with Table 1 (footnote 6) and Table 4 of the problem formulation carp data need only be evaluated for dioxin like chemicals.

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
		<p>dioxin-like chemicals, including PCB congener analysis, and in the draft BERA was a surrogate for other fish species for these chemicals. However, dioxins and furans (and dioxin-like PCBs) did not screen in, and were not further evaluated.</p> <p>For other chemicals evaluated using the tissue-residue approach, it is important to note that carp is a non-native nuisance species in the LWR and is not a receptor of concern for the ERA per EPA's problem formulation. Because of their size and unique bottom feeding they are not representative of other fish in the LWR. Sturgeon have a similar feeding mode but sturgeon tissue data are available for assessing risk to sturgeon.</p> <p>Additionally, it is important to note that the draft BERA did assess risks to piscivorous fish and wildlife from consumption of carp. Based on these factors, analysis of risk to carp is not likely to affect risk conclusions for any receptors.</p>	
Use of TTC/TSC methods for dietary approach	Non-directed comments: 128, 201, 206	<p>The TTC/TSC methods used in the draft BERA result in the exact same HQs as those resulting from Equation 1 of Problem Formulation Page 40. (See Attachment A). Dietary methods for the refined screen and BERA are equivalent.</p> <p>The text and tables in the SLERA and BERA will clearly show that TTC and TSC HQs are summed.</p>	<p>EPA agreed that the TTC and TSC methods are appropriate for use in the BERA because they result in the same HQs as those resulting from Equation 1 of Problem Formulation Page 40.</p> <p>The LWG agreed to check if there is a mistake in the dietary exposure estimates re: using tissue wet-weight conversion factors for sediment.</p>

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November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
Bird dioxin TRV	Non-directed comment: 200	The selected TRV was derived following the EPA-LWG agreed methods. No changes are proposed by the LWG in response to this comment.	EPA agreed that the bird dioxin TRV used in the draft BERA is appropriate for use in the revised BERA.
Inclusion of recently available osprey egg data	Non-directed comments: 49, 82, 154, 156, 163	The LWG agrees to use the newly available osprey egg data and these data will be fully characterized in the appropriate sections of the document (e.g., data, exposure assessment, and uncertainty analysis sections)	The LWG's general response is sufficient and appropriate to address this comment.
Clarifications needed	Non-directed comments: 44, 103, 71		<p>In the October 15, 2010 meeting the LWG and EPA agreed that specific clarifications be discussed between LWG and EPA technical leads. The LWG has tried unsuccessfully to schedule that discussion with EPA's BERA lead so will make the following changes in the revised BERA:</p> <p>With regard to comment 44, the LWG will provide a discussion of uncertainty regarding efforts to collect sufficient benthic invertebrate tissue biomass. Regarding comment 103, the specific text that EPA is referring to is not clear because the pages identified don't contain the referenced text, however, the intent of the comment is noted and the LWG will modify the text in this section acknowledging that tissue concentrations are based on</p>

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

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			composite samples and that TRVs are based on laboratory populations. No change will be made in response to comment 71 because the requested analysis is pertinent to the nature and extent of contamination rather than risks.
Issues needing discussion with EPA only if EPA does not agree with our written response			
Use of background/upstream data in BERA	Non-directed comment: 27, 70, 90, 116, 117, 127	<p>After tabulation of HQs and determination of potentially unacceptable risks, risks associated with regional/upstream data will be discussed as a component of describing the extent and magnitude of risks in the Risk Characterization section of the BERA.</p> <p>The revised BERA will further discuss upstream data elements related to uncertainty (e.g., size, numbers of samples)</p> <p>This information will be considered for COC recommendations in the Risk Management Recommendations Section.</p>	The LWG's general response is sufficient and appropriate to address this comment.
Further evaluation of lesion prevalence in fish	Non-directed comments: 63, 136	<p>The effects data available linking lesion prevalence to population level effects are sufficiently uncertain that the results of this LOE will be inconclusive regardless of the spatial scale at which data are analyzed. Therefore, results of this analysis would not affect risk conclusions.</p> <p>No changes are proposed by the LWG in response to</p>	In the October 15, 2010 meeting EPA agreed that no further analysis of lesion data are needed for the revised BERA.

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

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		this comment.	
SLERA/Refined screen process	Non-directed comments: 16, 77, 80, 81, 82, 123, 199, 201	<p>Comment 80 - All screening steps specified in the Problem Formulation except two were included. Justification for exclusion of these steps was provided in the BERA. No changes are proposed by the LWG in response to this comment.</p> <p>Comments 77, 81 and 199 - Describing differences in COPCs resulting from the stepwise refinement of the SLERA/Refined screen processes and increasing the complexity of the fish screen would not change the risk conclusions. No changes are proposed by the LWG in response to this comment.</p> <p>Comment 201 - Additional detail on dietary TTC/TSC screening process will be provided.</p> <p>Comment 123 - EPA stated in an e-mail dated September 12, 2008 that a Total DDX, rather than individual DDT congener approach should be used. Therefore, individual DDT congeners should not be retained as COPCs. Consistent with the resolution to comments 6 and 7, the LWG agrees to identify "potentially unacceptable risks" for COIs and COPCs with uncertain TRVs. Additionally, see above response to fish tissue TRVs.</p> <p>Comment 82 – This comment is addressed under osprey eggs.</p> <p>Comment 194 - Revisions to Section 5 of the BERA will be reflected in the SLERA.</p>	<p>The description of the SLERA and revised screen will be revised to clarify the steps that were followed. The specific chemicals that screened out at each step in the process will be clearly presented in the revised BERA. The SLERA will clearly state that all data, including the round 3B fish tissue data were screened.</p> <p>In addition to tables presenting the final COPCs to be addressed in the BERA, three tables will be included 1) COPCs resulting from the SLERA, 2) COPCs from the SLERA that drop out in the refined screen, 3) those chemicals with uncertain TRVs that are not assessed in the BERA.</p> <p>EPA agreed that species-specific screening is appropriate for the revised BERA.</p> <p>EPA agreed that for DDTs and DDT metabolites (DDD and DDE), the COPCs resulting from the SLERA will be based on the same NOAEL TRV used in the BERA (e.g., the fish tissue TRV is based on Total DDx so DDT, DDD, and DDE will not be identified as COPCs for the BERA).</p>

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

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Dietary uncertainty analysis	Non-directed comments: 105, 146, 150, 157	In cases where worst case dietary assumptions could result in a change from no HQ exceedances to some HQ exceedances or a large change in the magnitude of exceedance, a probabilistic analysis such as that presented for mink in figure 8-4 may provide insight into risks associated with different dietary assumptions. The LWG will explore the utility of such analyses.	The LWG's general response is sufficient and appropriate to address this comment.
Downstream data	Non-directed comments: 115, 126	The LWG contends that the CDF approach provides a good and proper means of presenting downstream data relative to the Study Area data. The LWG agrees to discuss the downstream data relative to TRVs in the risk characterization and uncertainties associated with downstream data (e.g., number of samples).	The LWG's general response is sufficient and appropriate to address this comment.
Use of BSAFs/BSARs in shore-bird risk calculations.	Non-directed comment: 158, 159, 160	<p>The FWM is used to predict tissue concentrations, so the empirical tissue concentration data were used to test model performance. We disagree that the BSAR acceptability criteria (significantly positive slope at a p of 0.05 and an r squared greater than 0.30) are too restrictive. This is a point that, if it was going to be raised, should have been raised in comments on the bioaccumulation modeling report, which was submitted to EPA on July 21, 2009.</p> <p>Where there was neither a field-collected or laboratory-exposed tissue, a dietary exposure was estimated based on a predicted tissue using a BSAR. Predicted concentrations are only presented for those chemicals where there was a relationship between sediment and tissue; therefore no predicted concentrations were provided for the dioxin/furan</p>	<p>In the October 15, 2010 meeting EPA and DEQ generally agreed with the LWG position that in contrast to EPAs comment, the BSAR acceptability criteria (significantly positive slope at a p of 0.05 and an r squared greater than 0.30) are not too restrictive, however the agency team did not internally reach consensus on this issue. Because the BSAR criteria are less restrictive than is generally accepted for scientific studies, the LWG will not change these criteria in the revised BERA.</p> <p>As requested in EPAs comments, the LWG will add to the discussion of</p>

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November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
		TEQ, total TEQ, aldrin, and sum DDE. No changes are proposed by the LWG in response to this comment.	uncertainty in predicted shorebird prey tissue concentrations. With regard to comment 160, the statement in the comment that "(t)ables with the predicted concentrations from the mechanistic model are presented in Table 3-7 from Attachment 3" is incorrect (there is no Table 3-7 from Attachment 3 and it is not clear what the comment is referring to. Predicted concentrations were calculated for the chemicals EPA asked about and this will be clearly presented in the revised BERA.
Fish dietary PCB and DDT TRVs	Non-directed comments: 198, 208	Table 4 of the Problem Formulation states "Use the dietary evaluation for PAH and metal contaminants only because tissue residue approach is much stronger for organics and non-regulated metals." Therefore, no dietary analysis of PCBs or DDTs was conducted for fish ROCs. No changes are proposed by the LWG in response to this comment.	The LWG's general response is sufficient and appropriate to address this comment.
Include HQs in summary tables	Non-directed comments: 20, 75, 77, 114, 173	Regarding comment 173, additional information will be included in the tables such as 11-1 summarizing risks assessed at the scale and complexity of the assessment endpoints. The LWG disagrees, however, that HQs should be presented in tables showing screening calculations.	EPA agreed that it is acceptable to present tables summarizing the chemicals with HQs greater than 1.0 using X's (e.g., Tables 7-39, 11-1), so long as subsequent tables summarizing the risks for a receptor

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November 18, 2010

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		The magnitude of HQs does not convey information about the magnitude of risks because it does not contain information about the dose-response relationship for the chemical-receptor pair. To show potentially very high HQs based on highly conservative screening assumptions would impart an overly conservative approximation of risks to the lay reader. Thus, HQs should only be presented for risk calculations commensurate with the scale and complexity of the assessment endpoints presented in the conceptual model.	group (e.g., Table 7-40) or multiple receptor groups (e.g., Table 11-2) provide sufficient information to characterize the magnitude, extent, and ecological significance of risks. EPA also agreed that HQs are not required for tables showing the results of screening calculations.
Remove table 7-40 "effects considerations" column	Non-directed comment: 144	Table 7-40 provides a summary of effects data uncertainties presented in the effects section (Section 7.2.3) and summarized in Table 7-21. Effects uncertainties are critical to risk conclusions so summarizing these uncertainties provides critical information for risk conclusions, thus this information should be retained in Table 7-40 and Table 11-2. No changes are proposed by the LWG in response to this comment.	This comment was not discussed in the October 15, 2010 meeting so in the revised BERA, the LWG will follow the general response.
Issues that do not need further discussion with EPA			
Use of COCs in the FS and beyond	Directed comments: 7, 11, 179, 180, 181 Non-directed comments: 28, 34, 55,	These comments were resolved in LWG-EPA meetings on Directed Comments	

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
	140		
Risk Management Recommendations	<p>Directed comments: 5, 6, 7, 8, 9, 10, 12, 26, 90, 145, 172, 178, 181, 184</p> <p>Non-directed comments: 29, 30, 34, 40, 46, 177, 183, 186,</p>	These comments were resolved in LWG-EPA meetings on Directed Comments	
Eco HQs \geq 1	<p>Directed comments: 7, 8, 10, 11, 12, 26, 145, 175, 178, 179, 180, 181, 184, 185</p> <p>Non-directed comments: 28, 38, 55, 140, 142, 145, 148, 174, 175,</p>	These comments were resolved in LWG-EPA meetings on Directed Comments	

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General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
	176		
Treatment of TZW	<p>Directed comments: 41, 61, 86, 99, 164, 165, 167, 169, 170, 171</p> <p>Non-directed comments: 1, 2, 31, 42, 51, 61, 62, 92, 93, 95, 98, 137, 167</p>	These comments were resolved in LWG-EPA meetings on Directed Comments	
Uncertainties that contribute to underestimating risk	<p>Directed comment: 143</p> <p>Non-directed comments: 14, 15, 18, 52, 113, 143,</p>	These comments were resolved in LWG-EPA meetings on Directed Comments	
Use factual statements	Non-directed comment: 22	References will be added to support scientific statements.	This comment was not discussed in the October 15, 2010 meeting so in the revised BERA, the LWG will follow the general response.
Address uncertainty in	Non-	The LWG agrees to discuss uncertainties associated	This comment was not discussed in

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November 18, 2010

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RI dataset	directed comment: 24	with sampling.	the October 15, 2010 meeting so in the revised BERA, the LWG will follow the general response.
Use of XAD vs. peristaltic data	Non-directed comment: 132	<p>XAD collection methods were specifically used to quantify organic chemical concentrations (PAHs, BEHP, PCBs and DDx) at levels below typical detection limits.</p> <p>XAD sample collection locations were paired with a subset of peristaltic pump sample locations (so not in the same "area" but actually same locations). In many cases, the XAD samples were the only samples that were analyzed for PCBs and DDx, so they are the only representation of those COCs. In other cases where both XAD and peristaltic samples were analyzed for the same chemicals, the peristaltic sample analytes were not detected, but the XAD analytes were.</p> <p>Since risk characterization was based on detected analytes, there is typically no overlap or issue in "dropping" the peristaltic results.</p> <p>No changes are proposed by the LWG in response to this comment.</p>	In the October 15, 2010 meeting the LWG agreed that comparison of XAD and peristaltic data on a point by point basis would be conducted and the results of this comparison would be presented in the uncertainty analysis in the revised BERA.
Population vs. organismal evaluation	Non-directed comments: 3, 138, 141, 162	It is appropriate to state the risk conclusions in terms of the assessment endpoints, which for fish (except juvenile Chinook salmon and lamprey) are populations of the receptor species. Those ROC-COPC pairs posing potentially unacceptable risks will be made consistent with resolution to HQs>1 discussed above.	The LWG's general response is sufficient and appropriate to address this comment.

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

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		Further discussion regarding the relationship between toxicity tests, TRVs, sampling, and populations will be added.	
Calculation of AWQC PCB and DDT direct exposure TRVs	Non-directed comments: 88, 89	<p>Chlordane, heptachlor, and heptachlor epoxide do not screen in as COPCs and for this reason derivation of direct exposure TRVs will not result in different risk conclusions. This is because under EPA water quality criteria methods, the bioaccumulation TRVs are necessarily more conservative than the direct exposure TRVs.</p> <p>Direct exposure TRVs were derived following EPA water quality criteria methods. The LWG agrees to present all data and calculations for derivation of the PCB and DDT TRVs.</p>	The LWG's general response is sufficient and appropriate to address this comment.
Weight of evidence analysis	Non-directed comment: 13	<p>Multiple lines of evidence were used only for benthic invertebrates, fish, and osprey eggs. The relative strengths of the LOEs used to characterize risks are dependent on the specific exposure and effects data available for each COPC so a generic approach is not appropriate.</p> <p>When the different LOEs used to assess risk result in conflicting risk estimates, the LWG will discuss the relative strength of the LOEs in the risk characterization and use this information in making risk conclusions.</p>	The LWG's general response is sufficient and appropriate to address this comment.
Requests to add info/revise document that are not likely to	Non-directed comments:	The LWG will add information/expand the discussion if it results in better readability of the documents, a more factual presentation of the issue, or clearer risk	This comment was not discussed in the October 15, 2010 meeting so in the revised BERA, the LWG will follow

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General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
substantially alter the outcome of the BERA	21, 56, 64, 74, 84, 94, 107, 108	conclusions.	the general response.
Benthic RA	Non-directed comments: 4, 73, 76, 83, 96, 97, 100, 101	Comments on the benthic risk assessment will be addressed in separate discussions considering EPA's comments on Section 6 of the BERA.	
Agree with revision	Non-directed comments: 19, 25, 32, 33, 35, 36, 39, 45, 48, 50, 53, 54, 57, 58, 59, 60, 65, 66, 67, 68, 69, 72, 78, 87, 90 (re: aluminum), 91, 102, 103, 104, 105, 111, 116, 117, 118, 121, 125, 129, 130, 133, 134, 152,	The LWG agrees with EPA's comment and will implement as requested.	

General Responses to EPA's Non-Directed Comment Key Issues on the Draft Baseline Ecological Risk Assessment
November 18, 2010

Issue Category	BERA Comments	General Response	Resolution
	153, 154, 155, 161, 166, 168, 187, 188, 189, 190, 191, 192, 194, 195, 196, 207, 209		